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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,288	02/13/2004	Takao Isogai	084335-0182	2549

22428 7590 01/09/2007

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EXAMINER	
ZHOU, SHUBO	
ART UNIT	**PAPER NUMBER**
1631	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/777,288	ISOGAI ET AL.	
	Examiner	Art Unit	
	Shubo (Joe) Zhou	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *2-4,13 and 14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 5-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/10/04,9/6/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Amendments

Applicants' election of Group I (claims 1 and 5-12 drawn to polynucleotides) and SEQ ID NO:899 in the response filed 10/18/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Accordingly, claims 1-14 are currently pending, claims 1 and 5-12 are under examination. Claims 2-4 and 13-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim.

The preliminary amendments to the specification filed 11/10/04 are acknowledged and entered.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because:

Non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c). The post office address for inventor Tetsuji Otsuki has been altered. While the alteration appears to be initialed but was not dated.

Information Disclosure Statement

The Information Disclosure Statements filed 11/10/04 and 9/6/05 have been entered and documents therein have been considered. Initialed copies of the form PTO-1449 are herein enclosed.

Specification

The specification is objected to because of the following including informalities:

The Abstract is objected to because it comprises more than one paragraph.

Trademarks are used in this application, such as GENBANK on page 4. Trademarks should be capitalized wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The disclosure is objected to also because it contains an embedded hyperlink and/or other form or browser-executable code. Such code is present in the specification at page 4 and elsewhere. Applicants are required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP ' 608.01.

Appropriate correction is required.

Claim Rejections-35 USC § 101 and § 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 and 5-12 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

Claims 1 and 5-12 are drawn to nucleic acids having a nucleotide sequence of SEQ ID NO:899, or a protein coding region thereof, or a polynucleotide hybridizable therewith, or encoding a partial amino acid sequence of the protein encoded by SEQ ID NO:899, or a recombinant vectors comprising the nucleic acid or cells comprising the recombinant vectors. The claimed nucleic acid is not supported by a specific asserted utility because none of the disclosed uses of the nucleic acid in the specification is specific and substantial. The specification discloses1995 clones isolated from multiple tissue libraries that are protein-encoding full-length cDNA clones. The specification provides a laundry list of applications of the 1995 clones. For the elected clone having the sequence of SEQ ID NO:899, the specification does not provide any function therefor. On page 3615, in a section where many clones are described to be homologous to a known gene, specification leaves a blank for clone CTONG2014959 – the clone that has the sequence of SEQ ID NO:899 (see page 9) – indicating that the nucleic acid has no homology with known genes. The specification does not provide a function for the gene or activity for the protein encoded thereby. Thus, it would require further research to determine the function of the gene and/or the activity of the protein encoded thereby in order to find a practical utility for the nucleic acid of SEQ ID NO:899.

Recently, in *In re Fisher,* a case analogous to the present application, the court, following an analysis of Nelson, 626 F.2d at 856, with regard to substantial utility, states that "it thus is clear that an application must show that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research." *In re Fisher*, 76 USPQ2d 1225 1230 (CAFC 2005). In the instant case, the application does not show that the claimed polynucleotide is useful to the public as disclosed in its current form, but that it may prove useful at some future date after further research.

Additionally, neither the specification as filed nor any art of record discloses or suggests any property or activity for the polypeptide encoded by SEQ ID NO:899 such that another non-asserted utility would be well established for the claimed nucleic acid.

Claim 1 is also rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 1 is drawn to a polynucleotide that is hybridizable to a polynucleotide comprising the sequence of SEQ ID NO:899. Given that the specification discloses that the nucleic acid of SEQ ID NO:899 is isolated from a human tissue library, the gene of the sequence must be part of the human genome. Also given that the claim does not require a particular hybridization condition of stringency, one skilled in the art would readily recognize that the native human DNA containing the gene representing the sequence of SEQ ID NO:899 would hybridize to the nucleic acid of SEQ ID NO:899 at certain hybridization conditions, such as at extremely low stringency. Thus, at least for one embodiment, claim 1 is directed to a DNA molecule which has the same characteristics as DNA found naturally and therefore does not constitutes patentable subject matter.

In the absence of the hand of man, naturally occurring products are considered non-statutory subject matter. Ex parte Siddiqui 156 USPQ 426 (1966). However, when purity results in new utility, patentability is considered. Merck Co. v. Chase Chemical Co. 273 F. Supp 68 (1967). See also American Wood v. Fier Disintegrating Co., 90 USPQ 127 (1948). Filing of evidence of a new utility imparted by the increased purity of the claimed product is suggested to obviate this rejection. For example, "An isolated DNA molecule..." is suggested.

The following is a quotation of the **first** paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 5-12 are rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention lacks a patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim 1 is also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claim 1 is drawn to nucleic acid molecules having a sequence that is hybridizable to a nucleic acid having the sequence of SEQ ID NO:899.

The claim is rejected mostly for the same reasons as those set forth in the "Revised Interim Written Description Guidelines Training Material" for similar claim limitations. The training material is available on the US PTO's website: http://www.uspto.gov/web/patents/guides.htm.

The claim is drawn to a genus of polynucleotides including any nucleic acids that are hybridizable to SEQ ID NO:899. Since the claim does not specify any stringency conditions for the hybridization, and does not contain functional limitations, the claim is broad and reads on virtually any nucleic acids because almost any nucleic acid will hybridize to a nucleic acid having the sequence of SEQ ID NO:899 at certain conditions such as that of extremely low stringency. Clearly, there is substantial variability among the species encompassed by the scope of the claim because the genus encompasses a variety of species with different structures and distinct functions.

A description of a genus may be achieved by means of a recitation of a representative number of species, falling within the scope of the genus, or by means of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. Regents of the University of California v. Eli Lilly & Co., 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In the instant case, the specification discloses only a species: the nucleotide sequence of SEQ ID NO:899, but, as set forth above, the lack of stringency of hybridization conditions and the lack of functional limitation would be expected to yield structurally unrelated nucleic acid molecules. Thus, the single disclosed species is not representative of the genus because there is no structural attribute or feature that is common to the members of the genus.

Therefore, one skilled in the art would reasonably conclude that applicant was not in possession of the claimed genus because a description of only one member of the genus is not representative of the broad genus of claimed invention.

Claim Rejections-35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, and 5-7 are rejected under 35 U.S.C. § 102(b) as being anticipated by Strausberg et al. (Proc. Natl. Acad. Sci. USA, Vol. 99, pages 16899-16903, 2002).

The claims are drawn to a nucleic acid comprising a sequence that is hybridizable to SEQ ID NO:899.

Strausberg et al. disclose a plurality of full-length cDNA sequences forming a Mammalian Gene Collection (MGC) including a cDNA sequence, deposited at GenBank as acc. # BC073975, that is 99.8% identical to the sequence of SEQ ID NO:899. See the attached sequence alignment between SEQ ID NO:899 and GenBank acc. # BC073975.

Given the high degree of identity shared by the two sequences, it would be readily apparent to one skilled in the art that the two would hybridize to each other at least at low stringency of hybridization, and even at high stringent conditions.

Strausberg et al. disclose that the clone with the sequence is comprised in the vector of pCMV-SPORT6, which is in an expressible manner under the control of CMV promoter, T7 promoter and SP6 promoter (see the attached map of pCMV-SPORT6, retrieved and printed

from website < http://mgc.nci.nih.gov/Vectors/vec_pcmv-sport6> on 12/22/06. The vector comprising the sequence of BC073975 is in host cells of DH10B. See the text description under "Features" immediately before the sequence alignment in the attached "sequence alignment between SEQ ID NO:899 and BC073975."

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strausberg et al., as applied to claims 1 and 5-7 above, in view of Lockhart et al. (WO97/10365, 1997).

Claims 9-12 are drawn to oligonucleotides, primers or probes comprising at least 15 nucleotides of the sequence of SEQ ID NO:899.

As applied to claims 1 and 5-7 above, Strausberg et al. disclose a plurality of full-length cDNA sequences forming a Mammalian Gene Collection (MGC) including a cDNA sequence, deposited at GenBank as acc. # BC073975, that is 99.8% identical to the sequence of SEQ ID NO:899. Strausberg et al. do not explicitly disclose oligonucleotide or primers or probes comprising at least 15 nucleotides of the sequence of SEQ ID NO:899.

However, Strausberg et al. motivate further studies with their isolated clones by stating that these clones be used for studies on system biology. See page 16902, right column. One having ordinary skill in the art would have been motivated by Strausberg et al. to use their clones for system biological studies including determining whether the same or similar gene is expressed in organisms that are systematically close to humans such as monkeys.

Lockhart et al. disclose a method of using microarrays containing probes/primers thereon for determining gene expression. Lockhart et al. state that traditional hybridization protocols for monitoring gene expression is problematic because tow or more gene products of approximately the same molecular weight will prove difficult or impossible to distinguish in a Northern blot or similar traditional techniques. However, oligonucleotide microarray can effectively be used to not only detect the presence of absence of garget nucleic acid sequences but to quantify the

relative abundance of the garget sequence in a complex nucleic acid pool. See pages 2-3. Lockhart et al. further state that "most preferable" oligonucleotide probes are those in from 15-40 nucleotides long. See page 5.

Therefore, one having ordinary skill in the art would have been motivated at the time the invention by Strausberg et al. to study the expression in related organisms of the gene represented by the cDNA of BC073975, and motivated by Lockhart et al. to use oligonucleotide microarrays to study the expression of BC073975 to take the advantages of oligonucleotide microarrays, and motivated by Lockhart et al. to select probes of 15-40 nucleotides long as they are the "most preferable."

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Strausberg et al., as applied to claims 1 and 5-7 above, in view of Possee, R.D. (Current Opinion in Biotechnology, Vol. 8, pages 569-572, 1997).

Claim is drawn to a method of producing a polypeptide comprising culturing a host cells comprising a vector comprising the polynucleotide of SEQ ID NO:899, or hybridizable thereto, and recovering the expression product.

As applied to claims 1 and 5-7 above, Strausberg et al. disclose a plurality of full-length cDNA sequences forming a Mammalian Gene Collection (MGC) including a cDNA sequence, deposited at GenBank as acc. # BC073975, that is 99.8% identical to the sequence of SEQ ID NO:899. Strausberg et al. do not explicitly disclose oligonucleotide or primers or probes comprising at least 15 nucleotides of the sequence of SEQ ID NO:899.

Strausberg et al. do not explicitly disclose a method of producing a polypeptide by culturing a cell comprising a vector containing the polynucleotide encoding the polypeptide.

However, Strausberg et al. motivate further study with their clones of cDNAs for "expression vectors" and "proteomics." See page 16902, right column.

Possee discloses a method using baculoviruses as an expression vector to express a protein with cDNA. The method comprises cloning cDNA in baculovirus vectors, and culturing cells containing the vectors to obtain protein. Possee states that the baculovirus expression vector provides a versatile and reliable system for the production of recombinant proteins in insect cells.

Therefore, one having ordinary skill in the art would have been motivated at the invention was made by Strausberg et al. to use their cDNA clones for expression studies by expressing the proteins, and would have been motivated by Possee to use the method he discloses for expressing the protein with the cDNA disclosed by Strausberg et al. to take advantage of the baculovirus system at least for its being versatile and reliable.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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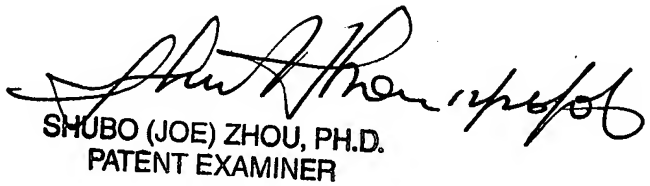

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